

Notice of Allowability	Application No.	Applicant(s)	
	09/931,701	OUTTRUP ET AL	
	Examiner	Art Unit	
	William W. Moore	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to The amendment filed 29 April 2005 and the replacement Drawingt filed 13 May 2005.
2. ☒ The allowed claim(s) is/are 52-80.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| <ol style="list-style-type: none"> 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>20040702</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
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EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Amend claims 65 and 74-76 thus:

65. (Amended) A subtilase of claim ~~64~~ 59, which consists of the amino acid sequence of amino acids 1 to 269 of SEQ ID NO: 2.
74. (Amended) 74. (Amended) A ~~modified~~ subtilase of claim 52 which is a modified subtilase comprising a modification ~~mutation~~ of the ~~amino acid~~ sequence of amino acids from 1 to 269 of SEQ ID NO: 2, wherein the modification ~~mutation~~ comprises a substitution, a deletion, and/or an insertion at one of the positions 27, 36, 56, 76, 87, 96, 97, 98, 99, 100, 101, 103, 104, 120, 123, 129, 131, 132, 133, 143, 159, 167, 170, 192, 194, 206, 217, 218, 222, 224, 232, 235, 236, 245, 248, 252 and 274, wherein the modified subtilase has subtilase activity and each position corresponds to a position in the amino acid sequence of the mature subtilisin BPN' set forth in SEQ ID NO: 9.
75. (Amended) A modified subtilase of claim 74, wherein the modification ~~mutation~~ comprises at least one modification selected from the group consisting of K27R, *36D, T56P, N76D, N87S, A97N, A98AS, A98AS, N99ND, N99NR, N99A, N99T, R101G, P103A, V104A, V104I, V104N, V104Y, D120H, N123S, P129K, P131H, A133P, A133D, A133E, T143K, *159D, *159E, ~~Y167X~~, Y167A, ~~R170X~~, R170S, A194P, Q206E, F217R, N218S, M222S, M222A, T244S, A232V, K235L, Q236H, Q245R, N248D, N252K and T274A.
76. (Amended) A subtilase of claim 74, wherein the modification ~~mutation~~ comprises V104N+R101G, K27R+V104Y+N123S+T274A, N76D+V104A,

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R101G+P103A+V104I+*159D+A232V+Q236H+Q245R+N248D+N252K; or any other combination of the modifications K27R, N76D, R101G, P103A, V104I, V104A, V104N, V104Y, N123S, *159D, A232V, Q236H, Q245R, N248D, N252K and T274A.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Elias J. Lambiris on 20 March 2006.

The following is an examiner's statement of reasons for allowance:

The replacement Drawing Figure filed 13 May 2005 is hereby ACCEPTED. The amendments filed 29 April 2005 overcome the rejections of record stated in the communication mailed 1 December 2004 where the recitations of percentage identity in claims 52-54 are supported by the paragraph spanning pages 12 and 13 of the specification and the recited percentage identities avoid the prior art cited at pages 11-14 of that communication and also avoid any double-patenting issues that might have implicated the commonly-assigned patent to Ness et al., US 6902922, made of record herewith. Recitations of residual activity in claims 55-59 are supported by disclosures at page 17, particularly lines 9-18, and at pages 50-52 of the specification. Recitations in claims 74-76 of particular positions for amino acid substitutions, deletions and insertions are supported by the disclosure at pages 5-8, and at lines 9-28 of page 16, of the specification and the modified subtilisins are enabled by the state of the art where these are all sites for prior art modifications ordinarily made in the class of "highly-alkaline" subtilases of which the *Bacillus clausii* subtilisin of SEQ ID NO:2 is a member. The above examiner's amendment corrects the dependency of claim 65, removes conflicting and ambiguous indications of substitutions at positions 167 and 170 in claim 75, and clarifies recitations of claims 74-76 by providing a uniform format throughout the claims for describing the modifications disclosed at lines 9-28 of page 16 of the specification.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

William W. Moore
20 March 2006


KATHLEEN M. KERR, PH.D.
SUPERVISORY PATENT EXAMINER